# Device Viewable Under an Imaging Beam

## Priority Claim

[0001] The present application is a continuation-in-part of U.S. Patent Application No. 10/394,007 filed March 24, 2003, the contents of which are incorporated herein by reference.

## Field of the Invention

[0002] The present invention relates generally to surgery under image guided navigation and more particularly relates to a method, device and system for surgical implantation of a medical device or the like, and/or postoperative evaluation of an implanted medical device or the like under image guidance.

## Background of the Invention

[0003] Stroke and cardiac disease remain a major cause of morbidity and result in profound suffering and expense. Increased awareness and improvements in diagnostic procedures have significantly increased the diagnosis of cervical and intracranial and cardiac vascular stenosis. A vascular stenosis is now being treated endovascularly at a significantly increased frequency. However, follow-up has predominantly been by angiography which evaluates the vascular contour but not the vascular wall. It is invasive, time consuming and expensive. Preliminary studies suggest that stent evaluation and restenosis pathophysiology can also be evaluated with Multi-detector Computed Tomography Angiography ("MDCTA") which would be a significant advantage of this technique over conventional angiography.

[0004] More specifically, endovascular therapy has ushered in a new age of minimally invasive vascular treatment. Endovascular devices have been rapidly developed and refined. Present technologies have enabled precise deployment of stents



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in much smaller arteries and have become more flexible and compliant so they can be navigated through tortuosities. At the same time there has been a growing pool of physicians trained in modern endovascular therapies so services are more widely available. However, the monitoring of these patients has become suboptimal because it relies on conventional angiography which is invasive and expensive. It also requires the patient to spend a full day removed from their daily activities. It also requires that some patients on anticoagulation briefly discontinue their therapy or be admitted to the hospital for an extended period of time. New MDCTA technology has not been widely used or validated for follow up. However, preliminary case studies seem to indicate that this technology is likely to provide additional beneficial information about the vascular wall and stent not obtainable from conventional angiograms. MDCTA is also non-invasive, requires a minimal amount of time and is less costly. MDCTA now has an axial resolution less than 0.5 mm and with the proposed development of new protocols and algorithms for image processing, this will be a superior tool to evaluate stenting and the etiology of any restenosis or stent failures. In particular, it will likely be able to separate negative remodeling from neointimal growth. It will also be able to evaluate for stent deformity and wall apposition as well as remodeling. MDCTA should also be applicable to other endovascular procedures such as follow up for aneurysm coilings.

[0005] Indeed MDCTA reflects a number of advances in medical imaging that allow real time and/or three-dimensional image gathering under Computed Tomography ("CT"), Magnetic Resonance Imaging ("MRI") or the like. For example, CT scanners such as the Toshiba Acquillion multi detector are capable of generating images in three different areas at frame rates of 13 frames a second, to thereby generate a three-dimensional rendering of the target area. Indeed, this and other advances in CT have led to the development of new CT applications including CT Angiography ("CTA"), and CT Perfusion ("CTP"). These imaging modalities are rapidly developing into powerful tools in the diagnosis and treatment of both ischemic and hemorrhagic stroke and bilary occlusion. See, for example, the following prior art references:

Kopp AF, Ohnesorge B, Flohr T, Georg C, Schroder S, Kuttner A, Martensen J, Claussen CD. [Cardiac multidetector-row CT: first clinical results of retrospectively ECG-gated spiral with optimized temporal and spatial resolution]Rofo Fortschr Geb Rontgenstr Neuen Bildgeb Verfahr. 2000 May;172(5):429-35.

Ohnesorge B, Flohr T, Becker C, Knez A, Kopp AF, Fukuda K, Reiser MF. [Cardiac imaging with rapid, retrospective ECG synchronized multilevel spiral CT]Radiologe. 2000 Feb;40(2):111-7

Achenbach S, Moshage W, Ropers D, Nossen J, Bachmann K. Non-invasive coronary angiography with electron beam tomography: methods and clinical evaluation in post-PTCA follow-up Z Kardiol. 1997 Feb;86(2):121-30.

Becker CR, Schoepf UJ, Reiser MF.Methods for quantification of coronary artery calcifications with electron beam and conventional CT and pushing the spiral CT envelope: new cardiac applications.Int J Cardiovasc Imaging. 2001 Jun;17(3):203-11.

Kopp AF, Schroeder S, Kuettner A, Baumbach A, Georg C, Kuzo R, Heuschmid M, Ohnesorge B, Karsch KR, Claussen CD. Non-invasive coronary angiography with high resolution multidetector-row computed tomography. Results in 102 patients.Eur Heart J. 2002 Nov;23(21):1714-25.

Achenbach S, Ulzheimer S, Baum U, Kachelriess M, Ropers D, Giesler T, Bautz W, Daniel WG, Kalender WA, Moshage W. Non-invasive coronary angiography by retrospectively ECG-gated multislice spiral CT.Circulation. 2000 Dec 5;102(23):2823-8.

Knez A, Becker A, Becker C, Leber A, Boekstegers P, Reiser M, Steinbeck G. [Detection of coronary calcinosis with multislice spiral computerized tomography: an alternative to electron beam tomographyZ Kardiol. 2002 Aug;91(8):642-9.

Mahnken AH, Sinha AM, Wildberger JE, Krombach GA, Schmitz-Rode T, Gunther RW. [The influence of motion artifacts conditioned by reconstruction, on the coronary calcium score in multislice spiral CT]Rofo Fortschr Geb Rontgenstr Neuen Bildgeb Verfahr. 2001 Oct;173(10):888-92.

[0006] However, despite these advances in medical device technology, and in particular stent technology and imaging technology, prior art stent technologies have

certain limitations when viewed under such CT machines, particularly due to beam hardening artefacts that are typically present, which thereby obscure the image and obviate or reduce the effectiveness of the CT machine as a post-operative diagnostic tool

[0007] Due to these present limitations using MDCTA, it is common to rely on classical angiography for postoperative evaluation of endovascular procedures, yet such angiographic methods are invasive and expensive. In the USA, an angiogram can cost up to $8000.00, yet a corresponding MDCTA could be offered for as little as $400.00. Additionally, endovascular ultrasound has significant associated risks and is not suitable for the small intracranial vessels. In the end, it is believed that MDCTA has the potential to provide good visualization of the lumen as well as the arterial wall and stent. MDCTA actually visualizes the stent better than fluoroscopy and will likely prove to be the preferred technique when background subtraction is used to increase vascular conspicuity. It is also believed that MDCTA would also enable more precise outcome evaluation and allow for investigation of the underlying pathophysiology as well as evaluation of the stents and devices used.

[0008] Polymer or lipid based drug delivery systems that can deliver drugs at a defined rate for up to five years from a single treatment have revolutionized medical therapy. Drug coated coronary stents have been shown to decrease restenosis rates in large clinical trials. See for example, the following references:

"Sirilimus eluting stents versus standard stents in patients with stenosis of the coronary artery", Moses *et al.* New England Journal of Medicine, page 1315-1323 October 2, 2003 Vol. 349, No. 14.

"Paclitaxel stent coating inhibits meointimal hyperplasia at 4 weeks in a porcine model of restenosis", Heldman *et al.* circulation 2001, 103-2289-95.

"A Paclitaxel eluting stent for the prevention of coronary restenosis", Park *et al.* New England Journal of Medicine 2003, Vol. 348, page 1537-45.

[0009] With respect to the drug delivery systems there are several types available at this time. These are principally those that are biodegradeable or those that are non biodegradeable. Biodegradable polymers release their loaded agents as they break down, while the matrix of non- biodegradable polymers remain intact even after all of the therapeutic agent has been released. These polymers release their loaded material by a process of either bulk erosion or surface erosion and diffusion or degradation. The polymers and co-polymers that are available at the present time include ethylene vinyl acetate ("EVAc"), a hydrophilic non biodegradable polymer, and biodegradeable polymers such as hydrophobic polymers such as poly[BIS(p-carboxyphenoxy)]propane-sebacic acid ("PCPP:SA"), hydrophilic polymers and fatty acid dimer-sebacic acid ("FAD:SA") polymers that deliver drugs including hydrophilic drugs and compounds

[0010] A process such as lyophilization can be used to load the polymer with the desired compound or drug or compounds or drugs. In this was PCPP:SA, a desired compound such as iodinated contrast material, and methyl chloride may undergo the lyophilization process to load the PCPP:SA with a material with the ability to attenuate x-ray radiation and be visible on a radiographic image.

**SUMMARY OF THE INVENTION**

[0011] In a first aspect of the invention there is provided a medical device made from a material operable to perform a therapeutic function of the device and wherein the material allows three-dimensional visualization of a surrounding tissue when the medical device is inserted into the tissue and viewed under an imaging beam.

[0012] It is therefore an object of the invention to provide a medical device that is viewable under certain imaging beams that obviates or mitigates at least one of the above-identified disadvantages of the prior art.

[0013] The medical device can be a stent and the surrounding tissue can be a lumen of a blood vessel. The stent can have a coating of a radioopaque material prior to insertion such that the stent that can be viewed during a conventional angiographic x-ray

DA/DSA insertion and wherein the coating diminishes after insertion such that the stent can be viewed under CT post insertion. The stent can be coated with at least one of an antibiotic and a chemotherapy drug. The stent can be coated with at least one drug selected from the group consisting of a drug that is therapeutically effective to decrease attachment of platelets to the stent and a drug that is therapeutically effective to decrease restenosis. The drug can be selected from the group consisting of aspirin, plavix or paclitaxel.

[0014] In a particular implementation of the first aspect, the device can be selected from the group of devices for the treatment of obstruction due to clot, plaque, atheroma, tumours, and treatments involving intimal hyperplasia and recurrent stenosis.

[0015] The material used to manufacture the medical device can be selected from the group consisting of plastic, composite carbon fiber and Inconel, nitinol, stainless steel, or a radio lucent material.

[0016] The imaging system can be a substantially real-time CT machine, such as the Toshiba Acquillon.

[0017] The medical device can have an image density of less than about 1200 Hounsfield Units. The image density can be less than about 900 Hounsfield Units. The image density can be less than about 700 Hounsfield Units. The image density can be less than about 400 Hounsfield Units.

[0018] The medical device can be a microcoil and the surrounding tissue is an aneurysm repaired with the microcoil.

[0019] The configuration and structure of the medical device can be chosen to combine with the properties of the chosen material to provide a reduced beam hardened artifact. For example, where the device is a stent and the struts of the stent can be aligned or otherwise configured to reduce the beam hardened artifact.

[0020] In another aspect of the invention there is provided an imaging processing unit for a CT machine comprising:

a means for receiving mutli-plane images of mammalian tissue;

a database of known medical devices and associated properties of the devices;

a means for determining whether an object detected in the received images matches with a known medical device in the database, the means for determining based on the associated properties;

means for applying a filter to the received images to enhance an image of the tissue that surrounds the implanted medical device based on the known associated properties; and,

means for presenting the image on an output device.

[0021] The database of known medical devices can include at least one of a stent and a microcoil. The associated properties in the database can include a Hounsfield unit measurement of the device.

## Brief Description of the Drawings

[0022] Embodiments of the invention will now be discussed, by way of example only, with reference to the attached Figures, in which:

Figure 1 is a representation of an imaging system;

Figure 2 is a side view of a prior art stent;

Figure 3 is a representation of a beam hardened artifact caused by the prior art stent of Figure 2 when viewed under the imaging system of Figure 1;

Figure 4 shows the beam hardened artifact of Figure 3 at a different angle;

Figure 5 shows the beam hardened artifact of Figure 4 at a different angle;

Figure 6 a side view of a stent in accordance with an embodiment of the invention;

Figure 7 is a representation of the stent of Figure 6 when viewed under the imaging system of Figure 1;

Figure 8 shows a microcoil in accordance with another embodiment of the invention;

Figure 9 is a partial view of the microcoil of Figure 8;

Figure 10 is a representation of a beam hardened artifact caused by a prior art microcoil when viewed under the imaging system of Figure 1;

Figure 11 is a representation of the microcoil of Figure 9 after insertion into a patient and when viewed under the imaging system of Figure 1;

Figure 12 is a representation of a beam hardened artifact caused by a prior art carotid stent when viewed under the imaging system of Figure 1; and,

Figure 13 is a representation of a carotid stent in accordance with another embodiment of the invention after the carotid stent has been inserted into a patient and when viewed under the imaging system of Figure 1.

## Detailed Description of the Invention

[0023] Referring now to Figure 1, an imaging system is indicated generally at 30. Imaging system 30 comprises a patient chamber 34, an image processing unit 38 and a display 42. Imaging system 30 can be based on any known or established imaging technology, but in a present embodiment is based on computed tomography (CT) having substantially the same functionality as a machine like the Toshiba Acquillon. Thus, patient chamber 34 is operable to capture images of a patient P in at least three planes, and processing unit 38 is operable to assemble those captured images to present a three-dimensional rendering of a target area within patient P on display 42. Images on display 42 can be navigated and/or viewed using the mouse and keyboard attached to processing unit 38, allowing the user to view a target area within patient P from any number of views. While not shown in Figure 1, image processing unit 38 can also be attached to other output devices in addition to display 42, such as a printer. Further, image processing unit 38 also typically includes a fixed storage device (such as a hard drive), a removable storage device (such as CD-Rewriter, or a tape drive) and a network interface card or other network interface means for connecting processing unit 38 to a network such as an intranet and/or the internet over which captured images can be delivered.

[0024] Referring now to Figure 2, a prior art conventional coronary stent is indicated at 50. Figure 2 shows stent 50 in isolation, however, for purposes of explaining the prior art, it is to be assumed that stent 50 has been implanted in a coronary artery of patent P.

[0025] Figure 3 shows an image 54 rendered on display 42 of system 30 of patient P. Image 54 shows a beam hardened artefact 52 as it is implanted inside a coronary artery 58 inside a heart 62 of patient P. The area identified as beam hardened artefact 52 is an inaccurate reproduction of stent 50 as it is implanted inside artery 58. The beam hardening artefact 52 is created by the material of stent 50. Accordingly,

system 30 is of limited value in performing post-operative evaluations of stent 50 and for determining whether any restenosis has occurred of coronary artery 58.

[0026] Figures 4 and 5 show additional images 54a and 54b, respectively, of different orientations of heart 62, which are readily produced on display 42 due to the imaging capability of system 30. In each image 54a and image 54b, stent 50 and the surrounding artery 58 are inaccurately reproduced due to beam hardening artefact 52 of stent 50. Thus, notwithstanding the great flexibility of system 30 in being able to provide a multiplicity of views of heart 62, in its current form stent 50 and system 30 do not provide meaningful images for post-operative evaluation of artery 58 and the progress of any restenosis that may be occurring in the lumen of artery 58 surrounding stent 50.

[0027] Figure 6, shows a medical device in accordance with an embodiment of the invention as a stent 150. Stent 150 from outward appearances is substantially the same as prior art stent 50, and indeed, in the present embodiment is designed to provide substantially the same mechanical and therapeutic functionality as prior art stent 50. However, in contrast to prior art stent 50, stent 150 is made from a material that has a selected radiopacity such that the appearance of stent 150 is preserved when stent 150 is exposed to the imaging beam of system 30 and presented on display 42. Thus, when stent 150 is implanted in heart 62, then in an image 154 of heart 62 generated by system 30, the appearance of stent 150 will be maintained when heart 62 and stent 150 are shown in display 42, as shown in Figure 7. Since image 154 has no beam hardened artefacts, it is now possible to examine the lumen of artery 58 surrounding stent 150, and thereby allow for an examination thereof for restenosis.

[0028] As will be appreciated by those of skill in the art, presence or absence of a beam hardening artefact can be measured according to the properties of the imaging system being used and in relation to the Hounsfield units associated with the particular material or tissue being exposed to the imaging beam. A relation between the linear attenuation coefficient ($\mu$) and the corresponding Hounsfield unit (H) can be expressed as:

$$H = \frac{\mu\text{Material} - \mu\text{Water}}{\mu\text{Water}} x1000$$

[0029] The value of the Hounsfield unit varies from -1000 (for air) to 1000 (for bone) to 3000, as more particularly shown in Table I.

Tissue Range of Hounsfield units
Table I[1]

| Material | Hounsfield Unit |
|---|---|
| Air | -1000 |
| Lung | -500 to -200 |
| Fat | -200 to -50 |
| Water | 0 |
| Blood | 25 |
| Muscle | 25 to 40 |
| Bone | 200 to 1000 |

[0030] Thus, in certain imaging systems materials with Hounsfield units exceeding about 1000 can be prone to creating beam hardening artefacts. Thus, presently preferred materials from which stent 150 can be manufactured to have reduced beam hardening artefacts include certain plastic, composite carbon fiber and Inconel metals that have similar mechanical properties to prior art stent 50 such that substantially the same therapeutic effect in stent 150 is achieved as was available in prior art stent 50. In any event, the chosen material for stent 150 has a level of Hounsfield density that diminish beam hardening artefacts to substantially preserve the appearance of the device under CT or other corresponding imaging beam.

[0031] It is thus presently preferred that stent 150 (or other medical devices according to the present invention) be made from a material or materials to have an overall image density of less than about 1200 Hounsfield Units. Such medical devices

[1] The foregoing equation and table is found in *Principles of Computerized Tomographic Imaging Parallel CT, Fanbeam CT, Helical CT and Multislice CT* by Marjolein van der Glas, August 29, 2000, http://www.ph.tn.tudelft.nl/~marlein/pdf/CT.pdf

can also have an overall image density of less than about 900 Hounsfield Units. Such medical devices can also have an overall image density of less than about 700 Hounsfield Units. Such medical devices can also have an overall image density of less than about 400 Hounsfield Units.

[0032] As previously discussed, other medical devices are also within the scope of the present invention. The medical devices within the scope of the invention include devices for the treatment of obstruction due to clot, plaque, atheroma, tumours or the like, and/or treatments involving intimal hyperplasia and recurrent stenosis after stent placement. An appropriate device is delivered into the vascular or bilary system under image guidance. The post placement follow up of the lumen is enabled by the diminished density and beam hardening artefact of the construct and coating of the stent.

[0033] A specific example of another medical device within the scope of the invention is shown in Figures 8 and 9, which shows a microcoil 250 for treatment of an aneurysm and which is introduced via a guiding cathether 240 and a microcatheter 245. As best seen in Figure 8, guiding cathether 240 is inserted through an incision 260 near the femoral artery or brachial artery or other suitable location and passed through the venous system of the patient until it reaches a blood vessel 264 proximal to an aneurysm 268 in the patient's head. (Further discussion of this procedure can be found in the Inventor's copending application entitled "Method and Apparatus for Reducing Exposure to an Imaging Beam" and filed in the US Patent Office on March 3, 2003, the contents of which are incorporated herein by reference.)

[0034] Figure 10 shows an image 254 of the resulting beam hardened artefact 252 when a prior art microcoil (not shown) is post-operatively examined using imaging system 30 has been previously inserted in the patient according to the method described in reference to Figure 8. The beam hardened artefact 252 thus renders it difficult, if not impossible, to accurately examine the prior art microcoil using imaging system 30.

[0035] However, as seen in image 354 shown in Figure 11, when microcoil 250 is inserted according to the method described with reference to Figure 8, then microcoil 250, the now-repaired aneurysm 268 and blood vessel 264 leading thereto are all visible on display 42 and therefore capable of post-operative evaluation.

[0036] Another medical device within the scope of the invention is a carotid stent, for placement in the carotid artery. Figure 12 shows an image 454 of a sagittal view of patient along a plane that includes the carotid artery 470 of the patient. Image 454 is characterized by a beam hardened artefact 452 through which the lumen of an implanted prior art stent can be identified, but artefact 452 is severe enough to obscure the lumen of the carotid artery 470, therefore preventing a determination as to whether restenosis is occuring in the lumen of artery 470 surrounding the prior art stent. However, as shown in Figure 13, when a carotoid stent 550 in accordance with an embodiment of the present invention is used, stent 550 and the lumen of artery 470 surrounding the stent 550 can be viewed and the occurence of restenonis determined.

[0037] In other embodiments of the invention, the specific structure and/or configuration and/or shape of stent 150 (or other medical device) is chosen to further reduce the device's overall radiopacity. For example, the weave of the stent's structure can be chosen to reduce the radiopacity, and therefore the measured level of Hounsfield units associated with the stent. Other aspects of the present invention provide a stent having a reduced number of passages of the stent or devices across the stenosis before dilating and deploying the stent in the stenosis. In certain prior art stents, it is necessary to cross the wire, pre-dilate, and deploy the stent posteriorly. As a further example, a stent in accordance with an embodiment of the present invention can include a self-expanding yet balloon mounted and intelligently be restrained. For example, the stent can be mounted on a balloon that is deployed by inflation of the balloon. Such a stent is self-expanding but is delivered on a balloon. The inflation of the balloon breaks the restraining polymeric bands and results in the self-expansion of the stent once the initial stimulus has been given. This polymeric material is drug-coated and thrombosis

resistant. This polymeric material helps restrain plaque and potential embolic material behind the stent. The overall configuration of the stent has reduced beam hardened artifacts post insertion when viewed under CT.

[0038] The number of passages of hardware across the stent or devices across the stent is reduced from five (as found in prior art stents) to two (according to an embodiment of the present invention) and thus, restrain against the wall of the vessel deep to the stent the material that would otherwise become potentially an embolic source. This can be helpful in reducing the risks of stroke after carotid stenting and in some circumstances can help reduce the need for distal flow protection devices which themselves have stroke risk.

[0039] In another variation of the present invention, shunt 150 is coated (either in its entirety or in particular locations) with an opacifier to temporarily increase the Hounsfield units associated with shunt 150 during its insertion, to allow shunt 150 to be inserted using traditional means. Such a coating would be configured to gradually abate and dissolve into the patient's blood stream, such that the radiopacity and associated Hounsfield units of stent 150 would decrease over time, such that under a post-operative CT evaluation, the Hounsfield units associated with stent 150 are low enough to allow proper visualization of the lumen of artery 58 surrounding stent 150. Suitable materials for coating shunt 150 include gold, iodine, ionic and non ionic iodinated compounds, ethiodol, and lipiodol, barium, tungsten, tantalum, gadolinium. Whatever coating is chosen, the amount and rate of dissolving of the coating is chosen to reduce toxicity experience by the patient during dissolution.

[0040] In a presently preferred embodiment, the aforementioned coating is a hydrophilic polymer containing a restenosis inhibiting drug and a density enhancing radiologic material such as lyophilizied iodinated contrast material, which is embedded into the polymer. This coating is then placed over a stent 150 that is made from a suitable material such as a plastic or metal, such as stainless steel, inconel or metal glass (materials already approved by The United States of America Food and Drug

Administration), or an optimal arrangement of strands of another metal can be used. The result is that stent 150 is both drug eluting and density eluting (i.e. the level of Hounsfield units associated with the stent decreases over time.)

[0041] In another embodiment of the invention, certain post processing software is provided in image processing unit 38 to maximize vascular conspicuity in conjunction with the known Hounsfield units and other imaging properties associated with stent 150 or other medical device in accordance with the present invention. For example, where a level of Hounsfield units associated with stent 150 is known, then upon detection by system 30 of an item within the patient at that particular level of Hounsfield units, then that information can be used to identify the item as stent 150 and then to further enhance the image of the surrounding vascular region based on the known imaging properties (ie. radiopacity, structure, etc.) and using known signal processing an filtering techniques.

[0042] While only specific combinations of the various features and components of the present invention have been discussed herein, it will be apparent to those skilled in the art that desired subsets of the disclosed features and components and/or alternative combinations of these features and components can be utilized, as desired. For example, the stents, coils and other medical devices according to the present invention can be coated with a material to decrease the risk of infection and restenosis, using techniques and compounds described in EP0797988A2 and EP1155689A2 to Angiotech Pharmaceuticals Inc. of Canada, and the University of British Columbia.

[0043] The present invention also provides certain novel methods for evaluating cervical and intracranial vascular stents using CT, including MDCTA, that is reliable and low cost and then to use these techniques for long term evaluation and outcome analysis of stenting. Sensitivity and specificity can then be determined for MDCTA by comparison to conventional catheter angiogram results. The radiographic density of the stent, coil or other device can be altered to enhance CT, X Ray, Ultrasound and MRI visibility of the lumen. For the purpose of enhanced accuracy of CT diagnostic imaging beam hardening artefacts will be reduced and/or minimized. The devices in the present

invention are in contrast to prior art devices that have been developed for conventional fluoroscopy guidance and thus are of a radiodensity or radiopacity that exceeds the needs of CT for clear visualization, this excess density creates unwanted beam hardening artefact.

[0044] Furthermore, the present invention allows for a relatively non-invasive means to visualize the lumen of a blood vessel surrounding a previously installed stent (or other site of an implanted medical device). Due to the reduced beam hardening artefacts of the stent, obscuration of the lumen is reduced. This results in the ability to visualize the lumen non-invasively as compared follow-ups conducted by invasive repeat catheter angiography, with its resultant risk of stroke, death and/or injury to an important vessel or to otherwise obscure a critical finding. CTA and CTP are relatively less invasive imaging modalities that have been shown to aid in the diagnosis and treatment of acute ischemic stroke. Both utilize high-speed spiral CT scanning and three-dimensional volumetric reconstruction software to create various types of images following injection of IV contrast solution. CTA can provide three-dimensional vascular delineation similar to other non-invasive techniques as well as visualization of adjacent non-vascular soft-tissue. CTA can also offer rapid volume acquisition, limited reconstruction artifact and scan completion during the period of peak intravascular contrast enhancement. Using CTA, it is often possible to see filling defect in a vessel as a result of contrast displacement by clot or thrombus. The sensitivity for detecting flow abnormality in vessels in the circle of Willis by CTA can be at least 89% when compared to digital subtraction angiography ("DSA"), and CTA does not carry the up to 5% risk of complication, and the up to 0.5% risk of permanent stroke that DSA has been shown to carry.

[0045] The above-described embodiments of the invention are intended to be examples of the present invention and alterations and modifications may be effected thereto, by those of skill in the art, without departing from the scope of the invention which is defined solely by the claims appended hereto.